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EXAMINER

HENDRICKS, KEITH D

ART UNIT PAPER NUMBER

1761

DATE MAILED: 03/12/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/040,394

Applicant(s)

SOE ET AL.

Examiner

Keith Hendricks

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 38-47 and 50-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-47 and 50-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/402,664.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-27 and 47\*, drawn to a lipase enzyme polypeptide, classified in class 435, subclass 198.
- II. Claims 28-37 and 48-49, drawn to a recombinant DNA molecule, host cell and method of culturing, classified in class 435, subclass 252.3, for example.
- III. Claims 38-46, 50-54 and 47\*, drawn to a dough or baked product containing lipase and method of making, classified in class 426, subclass 549.

\* Note that claim 47 is included in both groups I and III, insofar as it broadly encompasses multiple inventions. First, for example, a composition comprising water and the enzyme, which would be classified in Group I, and second, for example, flour, butter and the enzyme, which would be classified in Group III. Election of either Group I or Group III will result in claim 47 being examined to the extent that it reads upon said elected group. Appropriate amendment of claim 47 to fall within said elected group in a future response is necessary to remove potential double-patenting issues in any subsequent continuing applications.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are directed to products that are distinct both physically and functionally, and are therefore patentably distinct; and are not required one for the other. Although the DNA of group II can be used to direct the synthesis of the protein of group I, it can also be used in various other methods, for instance, it can be used as a probe in diagnostic methods or in gene therapy. Further, the protein of group I can be prepared by materially different processes such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product may be practiced with another materially different product, such as another lipase from alternative sources.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have completely different modes of operation and function, and the particulars of the DNA and host cell of Group II are not required for the method of preparing bread products of Group III.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During an electronic mail (e-mail) conversation with Angela Nigro on March 05, 2003, a provisional election was made without traverse to prosecute the invention of Group III, claims 38-47 and 50-54. Claims 1-37 and 48-49 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Specification*

The disclosure is objected to because of the following informalities: Page 65 of the specification is directed to a PCT official form for the Identification of Deposit of Microorganisms. Its placement within the specification is improper, as items such as figures or official forms are not part of the specification disclosure. Applicant is suggested to delete the page; however, applicant is cautioned against the introduction of new matter to (in the instant case, the deletion of material information from) the specification.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

i) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 47 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendment of claim 47 introduces the proviso of "wherein the dough component is an ingredient other than water." There is, however, no direct support for this negative limitation, found either in the specification or claims as originally filed. It is believed that this limitation was added in response to the conversation between applicants' representative and the examiner, regarding the restriction requirement and the note (also included above) that claim 47 broadly reads upon compositions, for example, containing water and the enzyme. Applicants, however, may not simply add arbitrary limitations to the originally-filed application, in response to communications from the Patent Office.

Furthermore, it is noted that the lipase enzyme *requires* water to be present, as it is a hydrolase-type enzyme, with the action of "hydrolyzing glycolipids".

Finally, it is noted that this limitation would not clearly remove the claim from being in both restriction groups I and III, noted above.

ii) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-39, 45-47 and 50-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In all claims in which it appears, the term "hydrolysing" should be spelled "hydrolyzing", as the accepted U.S. spelling. Similarly, the term "hydrolizes" (claims 50-52, 54) should be "hydrolyzes".
- The term "normally", as it appears, for example, in claims 38 and 45-47 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no means or measure by which one skilled in the art would know which glycolipids "normally" reside "in a flour". In fact, there is not even a specific flour recited, such that one skilled in the art would be able to determine this feature. One may not assume that certain lipids occur a certain percentage of the time in certain flours, and thus this should be assumed to be a "normal" frequency and/or amount.

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- The term "improved" in at least claims 38 and 45, is a relative term which renders the claim indefinite. Similarly, the term "reduced" is a relative term which renders the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Compare the use of these terms to that of, for example, the use of the term "reduction" in claim 40, where a base standard is provided, from which the claimed invention property is "reduced."
- Claim 39 is indefinite for the recitation of the phrase "wherein the dough does not contain added lipids." Initially, it is noted that this is not a positive recitation of an active method step. Secondly, it would be difficult or impossible for one skilled in the art to determine if certain lipids present were "added", or were naturally found in the dough components. Regardless, as several dough components contain lipids, including flour, these would necessarily constitute "added" lipids, or the act of "adding" lipids to the mixture.
- The term "triglyceride" is misspelled in the latest submission of claim 50.
- The term "unites", in claim 43, should be spelled "units".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38-42, 44-47 and 50-54 are rejected under 35 U.S.C. 102(b) as being anticipated by "Direct, A Newsletter from Danisco Ingredients", September 1996.

The *Direct* reference discloses a line of bakery lipase enzymes by the name of GRINDAMYL™ EXEL, where the enzyme "acts on flour lipids to produce a more stable dough system." Specifically disclosed is GRINDAMYL™ EXEL 26 lipase. Part of the activity of the enzyme is "providing a finer and more uniform crumb structure." "With these enzymes, bakers have gained a new tool for improving the dough stability, crumb structure, volume and softness of bread products and extending their shelf life." When the enzyme is combined with emulsifiers, they "contribute to a particularly successful synergy, resulting in a highly tolerant dough with excellent handling properties."

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Thus, the claimed invention is anticipated by the reference. Absent any clear and convincing evidence and/or arguments to the contrary, the enzyme would inherently possess the instantly-claimed properties for the ability to hydrolyze triglycerides, glycolipids and phospholipids. As the Patent Office does not possess the facilities to obtain, test and assay the activity of the enzyme, the burden shifts to applicant to demonstrate otherwise.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 40-43 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Direct Newsletter*, taken as cited above, in view of Olesen et al. (WO 94/04035, of record).

Olesen et al. disclose a method for the use of lipases in baking. Page 10 of the reference states that the microbial lipase preparation is preferably included in pre-mixes or flour "in the form of a dry product, e.g. a non-dusting granulate." Preferably, the use of additional fats in the dough is avoided. At pages 5-6 of the reference, it is stated that the use of a lipase results in "an improved dough consistency, an enlarged bread volume, and a better crumb structure as compared to the properties obtained when no lipase is added." Various microbial sources of the lipase are available, including *Aspergillus* species (pg. 6-7). At page 8, Olesen states that "normally, the enzyme preparation to be used in the present invention is [to] be added in an amount which, in the dough, results in a lipase activity in the range of 10-100,000 LU/kg of flour." Preferably, that range is stated to be 10-50,000 LU/kg, or lower.

As the *Direct Newsletter* reference does not specifically provide an amount utilized in the bakery doughs for effecting the described results, one of ordinary skill in the art would have found it obvious to turn to a general teaching in the art regarding such matters, which was provided, for example, by Olesen et al. Thus, it would not have involved an inventive step to ascertain the amounts of lipase generally used in the art for bakery flour doughs, and to have used the lipase described in the *Direct Newsletter* in similar amounts for producing the described effects on baked products.

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### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

i) Claims 38-46, 50-54 and 47 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 09/727,852. Although the conflicting claims are not identical, they are not patentably distinct from each other because each application claims the use of an enzyme (lipase) in dough, which hydrolyzes "compounds including a triglyceride, a glycolipid and a phospholipid."

ii) Claims 38-46, 50-54 and 47 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 09/723,253. Although the conflicting claims are not identical, they are not patentably distinct from each other because each application claims the use of an enzyme (lipase) in dough, which hydrolyzes "compounds including a triglyceride, a glycolipid and a phospholipid."

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

\*\* NOTE: Although not required, applicants are requested to supply the Office with the serial numbers of all related co-pending or allowed applications which pertain to the subject matter contained herein, including any pertaining to the enzymes themselves. This request was made in the '253 application in August of 2001, yet no mention of the instant application has been made by applicants since the filing of this application.



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iii) Applicant is advised that should claim 51 be found allowable, claim 52 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### *Conclusion*

**NOTE:** The reference to Angelino et al. (Proceedings of ESEGP-1) is not applicable as prior art under the statutes of 102 (a) or (b), which state:

(a) the invention was known or used by others **in this country**, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale **in this country**, more than one year prior to the date of application for patent in the United States.

While the reference appears to be published on April 09, 1997, which is the same day as applicants' earliest foreign priority date, it does present information which was made publicly available on December 2-4, 1996. However, as this conference was held in The Netherlands, it does not satisfy the requirements of the statutes recited above. In other words, it is not evidence that the invention described therein, to the use of GRINDAMYL™ EXEL 16 lipase in flour doughs, was available in public use or on sale in this country, before the invention thereof by the applicant for a patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703) 308-3959. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9565 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



KEITH HENDRICKS  
PRIMARY EXAMINER